K113401

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FEB - 7 2012

510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6146 Fax: 847-534-6146
Date Prepared:	
Trade Name:	**Ortho-1**
Common Name:	Orthodontic Adhesive
Product Code:	DYH
Classification/Name:	Bracket Adhesive Resin **Class II per 21 CFR 872.3750**

Predicate Devices:

Ortho-1 is substantially equivalent to Ortho-One by Bisco, Inc. Schaumburg IL K962946; Light Bond (Quick Cure) by Reliance Orthodontic Products Inc., Itasca IL K001048: And Bisco Etchants by Bisco, Inc. Schaumburg IL K101485.

Indications for Use:

The indication for use of **Ortho**-1 is a bracket bonding system in the oral cavity of dental patients.

Description of Applicant Device:

Ortho-1 is an orthodontic no-mix direct bonding system consisting of Paste, a Primer, and **Liquid Etchant**. The micromechanical bond to enamel utilizes the acid etch technique and Bisco's unique composite chemistry. **Ortho-1** will bond to brackets (such as metal, plastic, or porcelain) without additional conditioners. **Ortho-1** will also bond any type of bracket to properly conditioned dental material restorative materials (such as porcelain, composites, and metal).

Technological Characteristics:

All components of **Ortho-1** are based upon industry standard monomer chemistry and are found in the legally marketed predicate device Ortho-One (K962946) and Bisco Etchants K101485. Comparisons of the chemical composition of **Ortho-1** to the predicates are provided on the following page:

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Chemical Composition	Ortho-One K962946	Ortho-1
Chemical Cure	X	X
Solvent free, unfilled, methacrylate based primer	X	X
Silica filled methacrylate based paste	X	X

Chemical Composition	Bisco Etchants K101485	Liquid Etchant
Phosphoric Acid	X	X

Performance Data:

The physical/mechanical properties of Ortho-1 and Liquid Etchant were tested in the lab using R&D testing protocols. The information provided in this 510(k) of **Ortho-1** and **Liquid Etchant** compared to the predicates demonstrates that they are effective for its indications of use. A comparison of the physical/mechanical properties are included below:

Physical / Mechanical Property Comparison	Ortho-One K962946	Ortho-1
Low viscosity Primer	X	X
Tacky Paste	X	X
Medium viscosity paste		X
Low viscosity paste		X
High viscosity paste	X	X

Physical / Mechanical Property Comparison	Bisco Etchants K101485	Liquid Etchant
Low viscosity, semi-gel	X	X
Green color	X	X

Biocompatibility:

An evaluation of biocompatibility was conducted to determine the safety of **Ortho-1** and **Liquid Etchant**. **Ortho-1** had cytotoxicity-agarose diffusion testing conducted. The conclusions of the safety evaluations are that **Ortho-1** and **Liquid Etchant** are safe for their intended uses.

Conclusion:

Side by side comparisons clearly demonstrate that the applicant devices are substantially equivalent to other legally marketed devices. It is concluded that the information supplied in this submission has proven the safety and efficacy of these products.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 7 2012

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
BISCO, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K113401
Trade/Device Names: Ortho-1
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: November 15, 2011
Received: November 17, 2011

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K113401

Device Name: Ortho-1

Indications for Use:

The indication for use of Ortho-1 is a bracket bonding system in the oral cavity of dental patients.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113401